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Fredrikson & Byron, P.A. Intellectual Property Group, MDT Patents 200 South Sixth Street, Suite 4000 Minneapolis, MN 55402			EXAMINER SANDS, DAVIN	
			ART UNIT 3769	PAPER NUMBER
			NOTIFICATION DATE 04/28/2011	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ip@fredlaw.com

Office Action Summary

Application No.

10/687,389

Applicant(s)

OSORIO ET AL.

Examiner

DAVIN SANDS

Art Unit

3769

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-8, 10-12, 14 and 33-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 2-8, 10-12, 14 and 33-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 April 2008 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 2 December 2010
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Drawings

The drawings are objected to because the label of the y-axis in figure 22 is misspelled; "mamimum" should be changed to "maximum". Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claims 4-5 and 42 are objected to because of the following informalities: the "event" recited throughout these claims should be modified to "neurological event" to bring them more in keeping with the respective independent claims and to make the antecedent basis more clear. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11, 35, and 40-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11, 35, and 41 recite the limitation "wherein the lowest relative severity score associated with clinical manifestations or other behaviors indicative of a nervous system disorder activity may be used to minimize a probability of missing clinical events." The use of the term "may be used" in line 5 of each claim makes it unclear whether the limitation is positively claimed. For the purpose of this action, the examiner interprets this language to mean that the limitation is not positively claimed.

Claim 40 recites the limitation "the detection cluster" in lines 2 and 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2-8, 10-12, and 33-43 are rejected under 35 U.S.C. 102(b) as being anticipated by WIPO International Publication WO 00/10455 A1 to Echauz J et al. (hereafter referred to as Echauz).

Regarding claim 2, Echauz discloses a system and method for predicting a probability of a seizure occurrence within various time frames based on features extracted from neurological data. This is interpreted as a method for scoring a severity (predicting a probability) of a neurological event associated with a nervous system disorder (occurrence of a seizure), comprising the steps described below, all of which are performed using a processor (Fig. 5).

Echauz further teaches that “pre-ictal prodromes are specific pre-ictal patterns which occur on the EEG ... which herald seizure onset” (pg. 37, ln. 19-21) and that the system can include “prodrome detection, which can be either quantitative, feature driven, or accomplished via pattern matching” (pg. 38, ln. 21-23). This is interpreted as determining using a processor (pattern matching) that a sensed neurological signal (patterns on the EEG) represents a neurological event (prodrome).

Echaz further teaches that a "historical feature vector is generated that contain counts of the occurrence of a pre-ictal prodrome in the last "n" time windows (by template matching or frequency/time domain characteristics)" (pg. 39, ln. 1-3) where the prodromes "cluster together prior to seizure onset" (pg. 38, ln. 9) and "the patient may flag that a seizure has occurred, and buffered data will be stored ... and then update training of the intelligent prediction subsystem will take place to reflect this occurrence" (pg. 14, ln. 23-27). This is interpreted as identifying using a processor (generated historical feature vector) a feature of the neurological event to use in scoring (count of prodrome occurrence), wherein the neurological event is a detection cluster event (prodrome cluster) or a reported event (buffered data from patient flagged seizure).

Echaz further teaches that "these feature vectors are fed into the series of wavelet neural networks and probabilities of seizure occurrence for each time horizon are continuously calculated" (pg. 39, ln. 5-7). This is interpreted as computing using a processor (continuously calculated) a score of relative severity of the neurological event (probability of seizure occurrence) using the identified feature (feature vectors).

Echaz further teaches that "higher actual probabilities occur when several pre-ictal prodromes are detected in a 3 hour period" (pg. 39, ln. 7-8). This is interpreted as ranking using a processor (higher calculated probabilities) the neurological event (prodrome occurrence) by severity relative to at least one other scored neurological event (higher probability of seizure occurrence than for previously detected prodromes).

Regarding claim 3, Echauz discloses all the limitations of claim 2 and further teaches that the prodromes “often cluster together prior to seizure onset” (pg. 38, ln. 9) and “increase in their frequency of occurrence, their amplitude or their duration as the seizure approaches” (pg. 37, ln. 21-23). This is interpreted to mean that the identified feature is a number of detections within a cluster (frequency of prodrome occurrence), or a duration of a detection (prodrome duration).

Regarding claim 4, Echauz discloses all the limitations of claim 2 and further teaches that the “portable unit triggers visual displays and auditory cues of this [seizure probability] information” (pg. 10, ln. 23-24). This is interpreted as communicating the ranked events (seizure probability information) to an external device (visual displays).

Regarding claim 5, Echauz discloses all the limitations of claim 2 and further teaches that the “portable unit triggers visual displays and auditory cues of this [seizure probability] information” (pg. 10, ln. 23-24). This is interpreted as displaying (visual displays) the ranked events (seizure probability information).

Regarding claim 6, Echauz discloses all the limitations of claim 2 and further teaches that “the signal processing required to extract the features and perform prediction is most likely performed in the implanted unit due to its proximity to the brain activity or other physiological signals” (pg. 10, ln. 25-27). This is interpreted to mean that the ranking (prediction) is performed by an implanted device.

Regarding claim 7, Echauz discloses all the limitations of claim 2 and further teaches that a "historical feature vector is generated that contain counts of the occurrence of a pre-ictal prodrome in the last "n" time windows (by template matching or frequency/time domain characteristics)" (pg. 39, ln. 1-3). This is interpreted to mean that identifying a feature comprises using algorithm-based (template matching) measures of activity of the nervous system disorder (pre-ictal prodrome).

Regarding claim 8, Echauz discloses all the limitations of claims 2 and 5 and further teaches that the prodromes "are specific pre-ictal patterns which occur on the EEG" (pg. 37, ln. 20) and "increase in their frequency of occurrence, their amplitude or their duration as the seizure approaches" (pg. 37, ln. 21-23). This is interpreted to mean that the nervous system disorder is a seizure and that computing the score (assessing probability based on a feature vector) is relating duration (prodrome duration), intensity (prodrome amplitude), and extent of electrographic spread (pre-ictal EEG pattern) of the nervous system disorder (seizure).

Regarding claim 10, Echauz discloses all the limitations of claim 2 and further teaches that the prodromes "often cluster together prior to seizure onset" (pg. 38, ln. 9) and "increase in their frequency of occurrence, their amplitude or their duration as the seizure approaches" (pg. 37, ln. 21-23). This is interpreted to mean that the identified

feature is a number of detections within a cluster (frequency of prodrome occurrence), or a duration of a detection (prodrome duration).

Regarding claim 11, Echauz discloses all the limitations of claim 2 and further teaches that there are "predetermined probability measures to control when alerts are generated and/or when preventative action is taken" (pg. 39, ln. 21-23). This is interpreted to mean that computing the score (determining probability) involves computing a relative severity minimum (predetermined thresholds of probability for control).

Regarding claim 12, Echauz discloses all the limitations of claim 2 and further teaches that "physiologic sensors such as those which monitor heart rate variability, vagus nerve impulses, brain blood flow, serum chemistry (for example, epinephrine levels), may also be useful to obtain physiologic signals" (pg. 9, ln. 13-16). This is interpreted to mean that the sensed neurological signal (physiologic signal) is received from a monitoring element (sensor) and could be a chemical signal (serum chemistry), a biological signal (brain blood flow), a heart rate signal (heart rate variability), or a peripheral nerve signal (vagus nerve impulses).

Regarding claim 33, Echauz discloses a system and method for predicting a probability of a seizure occurrence within various time frames based on features extracted from neurological data. These features include pre-ictal prodromes which are

"specific pre-ictal patterns which occur on the EEG ... which herald seizure onset" (pg. 37, ln. 19-21), and tend to "cluster together prior to seizure onset" (pg. 38, ln. 9). This is interpreted as a method for determining the severity (predicting a resulting probability of seizure occurrence) of a detection cluster (prodrome cluster), comprising the steps described below, all of which are performed using a processor (Fig. 5).

Echaz further teaches that the system can include "prodrome detection, which can be either quantitative, feature driven, or accomplished via pattern matching" (pg. 38, ln. 21-23). This is interpreted as determining using a processor (pattern matching) that a sensed neurological signal (patterns on the EEG) represents a detection cluster (prodrome cluster).

Echaz further teaches that a "historical feature vector is generated that contain counts of the occurrence of a pre-ictal prodrome in the last "n" time windows (by template matching or frequency/time domain characteristics)" (pg. 39, ln. 1-3). This is interpreted as identifying using a processor (generated historical feature vector) a feature in the detection cluster (count of prodrome occurrence).

Echaz further teaches that "these feature vectors are fed into the series of wavelet neural networks and probabilities of seizure occurrence for each time horizon are continuously calculated" (pg. 39, ln. 5-7), and that "the basic implementation of a T -minute WNN [wavelet neural network] predictor is a multiple-input, single-output transformation" (pg. 27, ln. 11-12) which is shown below (pg. 27, ln. 13):

$$\hat{P}_r = \frac{1}{1 + e^{-u}},$$

$$u = \sum_{j=1}^M c_j \psi_{A_j, b_j}(x) + c_1^{in} x_1 + \dots + c_n^{in} x_n + c_0^{in},$$

$$\psi_{A_j, b_j}(x) = \psi(\sqrt{(x - b_j)A_j(x - b_j)^T}),$$

$$\psi(x) = \min\{\max\{\frac{1}{2}(1 - |x|), 0\}, 1\} \cos(\frac{3}{2}\pi x),$$

This is interpreted as computing using a processor (continuously calculated) a score of relative severity of the detection cluster (probability of seizure occurrence) using the identified feature (feature vectors), wherein the computed score is selected from a range (single output from multiple inputs) of at least three values (c_1 , c_n , c_0) including an upper value and a lower value (inherent to any range of two or more unequal numbers).

Echaz further teaches that "higher actual probabilities occur when several pre-ictal prodromes are detected in a 3 hour period" (pg. 39, ln. 7-8). This is interpreted as ranking using a processor (higher calculated probabilities) the detection cluster (prodrome cluster) by severity relative to previously scored detection clusters (higher probability of seizure occurrence than for previously detected prodrome clusters).

Regarding claim 34, Echaz discloses all the limitations of claim 33 and further teaches that the prodromes "increase in their frequency of occurrence, their amplitude or their duration as the seizure approaches" (pg. 37, ln. 21-23). This is interpreted to mean that the identified feature is a number of detections within a detection cluster (frequency of prodrome occurrence in the cluster), or a detection cluster severity (prodrome amplitude).

Regarding claim 35, Echauz discloses all the limitations of claim 33 and further teaches that there are "predetermined probability measures to control when alerts are generated and/or when preventative action is taken" (pg. 39, ln. 21-23). This is interpreted to mean that computing the score (determining probability) involves computing a relative severity minimum (predetermined thresholds of probability for control).

Regarding claim 36, Echauz discloses all the limitations of claim 33 and further teaches that the "feature set is systematically pared down for each individual patient (during "off-line" analysis) to a subset of core parameters ... this process of adaptive training will take place periodically throughout the life of the device" (pg. 8, ln. 11-15), and "patient interaction with the system in the event of false positive alarms will further facilitate "on-line" learning of the intelligent prediction system" (pg. 14, ln. 21-22). This is interpreted as allowing a user (patient) to exclude a certain event from being scored (events are excluded by rejecting features from the feature subset that were involved in their detection, which directly resulted from patient interaction through identifying false positives, and thereby training the system to ignore such events in the future).

Regarding claim 37, Echauz discloses all the limitations of claim * and further teaches that a "historical feature vector is generated that contain counts of the occurrence of a pre-ictal prodrome in the last "n" time windows" (pg. 39, ln. 1-2). This is interpreted to mean that the steps of identifying, computing the score, and ranking can

only occur after the detection cluster has ended (historical feature vector, used in all three steps, contains prodrome counts from previous time windows).

Regarding claim 38, Echauz discloses a system and method for predicting a probability of a seizure occurrence within various time frames based on features extracted from neurological data. These features include pre-ictal prodromes which are "specific pre-ictal patterns which occur on the EEG ... which herald seizure onset" (pg. 37, ln. 19-21). This is interpreted as a method for determining the severity (predicting a resulting probability of seizure occurrence) of a detected neurological event (pre-ictal prodrome), comprising the steps described below, all of which are performed using a processor (Fig. 5).

Echauz further teaches a "system for monitoring electrical activity of the brain" (pg. 39, ln. 13). This is interpreted as receiving (monitoring) a neurological signal (brain electrical activity).

Echauz further teaches that the system can include "prodrome detection, which can be either quantitative, feature driven, or accomplished via pattern matching" (pg. 38, ln. 21-23). This is interpreted as processing using a processor (pattern matching) the neurological signal (patterns on the EEG) to detect a neurological event (prodrome detection).

Echauz further teaches that a "historical feature vector is generated that contain counts of the occurrence of a pre-ictal prodrome in the last "n" time windows (by template matching or frequency/time domain characteristics)" (pg. 39, ln. 1-3). This is

interpreted as characterizing using a processor (generated feature vector) a feature (count of prodrome occurrence) of the detected neurological event (prodrome occurrence).

Echaz further teaches that "these feature vectors are fed into the series of wavelet neural networks and probabilities of seizure occurrence for each time horizon are continuously calculated" (pg. 39, ln. 5-7), and that "the basic implementation of a T-minute WNN [wavelet neural network] predictor is a multiple-input, single-output transformation" (pg. 27, ln. 11-12) which is shown below (pg. 27, ln. 13):

$$\begin{aligned}\hat{P}_T &= \frac{1}{1 + e^{-u}}, \\ u &= \sum_{j=1}^M c_j \psi_{A_j, b_j}(x) + c_1^{in} x_1 + \dots + c_n^{in} x_n + c_0^{in}, \\ \psi_{A_j, b_j}(x) &= \psi(\sqrt{(x - b_j)A_j(x - b_j)^T}), \\ \psi(x) &= \min\{\max\{\frac{3}{2}(1 - |x|), 0\}, 1\} \cos(\frac{3}{2}\pi x),\end{aligned}$$

This is interpreted as computing using a processor (continuously calculated) a score of relative severity of the neurological event (probability of seizure occurrence) based on the feature (feature vectors), wherein the computed score is selected from a range (single output from multiple inputs) of at least three values (c_1 , c_n , c_0) including an upper value and a lower value (inherent to any range of two or more unequal numbers).

Regarding claim 39, Echaz discloses all the limitations of claim 38 and further teaches that "higher actual probabilities occur when several pre-ictal prodromes are detected in a 3 hour period" (pg. 39, ln. 7-8). This is interpreted as ranking the neurological event (prodrome occurrence) relative to at least one other neurological

event (higher probability of seizure occurrence than for previously detected prodrome clusters), the ranking based on the severity score (higher calculated probabilities).

Regarding claim 40, Echauz discloses all the limitations of claim 39 and further teaches that the prodromes "cluster together prior to seizure onset" (pg. 38, ln. 9) and "increase in their frequency of occurrence, their amplitude or their duration as the seizure approaches" (pg. 37, ln. 21-23). This is interpreted to mean that the characterized feature is a number of detections within a detection cluster (frequency of prodrome occurrence in the prodrome cluster), or a detection cluster severity (prodrome amplitude within the prodrome cluster).

Regarding claim 41, Echauz discloses all the limitations of claim 39 and further teaches that there are "predetermined probability measures to control when alerts are generated and/or when preventative action is taken" (pg. 39, ln. 21-23). This is interpreted to mean that computing the score (determining probability) involves computing a relative severity minimum (predetermined thresholds of probability for control).

Regarding claim 42, Echauz discloses all the limitations of claim 39 and further teaches that the "feature set is systematically pared down for each individual patient (during "off-line" analysis) to a subset of core parameters ... this process of adaptive training will take place periodically throughout the life of the device" (pg. 8, ln. 11-15),

and "patient interaction with the system in the event of false positive alarms will further facilitate "on-line" learning of the intelligent prediction system" (pg. 14, ln. 21-22). This is interpreted as allowing a user (patient) to exclude a certain event from being scored (events are excluded by rejecting features from the feature subset that were involved in their detection, which directly resulted from patient interaction through identifying false positives, and thereby training the system to ignore such events in the future).

Regarding claim 43, Echauz discloses all the limitations of claim 38 and further teaches that a "historical feature vector is generated that contain counts of the occurrence of a pre-ictal prodrome in the last "n" time windows" (pg. 39, ln. 1-2). This is interpreted to mean that the steps of identifying, computing the score, and ranking can only occur after the detection cluster has ended (historical feature vector, used in all three steps, contains prodrome counts from previous time windows).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Echauz as applied to claim 2 above, and further in view of U.S. Patent US 6,463,328 to John

(hereafter referred to as John). Echauz discloses all the limitations of claim 2, but does not teach that the nervous system disorder is a peripheral nervous system disorder, a mental health disorder, or a psychiatric disorder. John discloses a system for monitoring and treating brain dysfunction, and teaches that "since EEG and/or MEG are currently the least expensive techniques appropriate for monitoring the overall state of the CNS on an ongoing basis, they are the suitable measures to be used as indicators of CNS state during the treatment process in disorders such as coma or psychiatric disorders" (col. 6, ln. 26-31). It would have been obvious to one of ordinary skill in the art at the time of the invention to have used the system for detecting neurological events indicative of seizure onset of Echauz to monitor and assist in the treatment of other disorders that cause neurological abnormalities, such as psychiatric disorders, as evidenced by the teachings of John. This is interpreted to mean that the nervous system disorder can be a psychiatric disorder.

Response to Arguments

Applicant's arguments, see page 6, filed 13 July 2010, with respect to the rejection(s) of claim(s) 2-8, 10-12, 14, and 33-43 under 35 USC 101 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Echauz and John as described above.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent US 6,304,775 to Iasemidis et al. discloses a similar system for using neurological data for predicting that a seizure is likely to occur and when it will occur.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVIN SANDS whose telephone number is 571-270-1842. The examiner can normally be reached on Monday - Friday, 7:30am - 3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sam Chuan Yao can be reached on 571-272-1224. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DAVIN SANDS/
Examiner, Art Unit 3769

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